UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,295	08/23/2001	Stephen C. Knight	VEK-001.01	1054

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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	09/938,295	KNIGHT, STEPHEN C.
	Examiner	Art Unit	
	RACHEL L. PORTER	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS,
> WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
>   after SIX (6) MONTHS from the mailing date of this communication.
> - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
> - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
>   Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
>   earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>11 October 2007</u>.
2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
   closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>2-4,9-12,17 and 19-44</u> is/are pending in the application.
   4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) <u>2-4,9-12,17 and 19-44</u> is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a) ☐ All   b) ☐ Some * c) ☐ None of:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. _____.
    3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
       application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
   Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1.   This communication is in response to the amendment filed 10/11/07. Claims 2-

4,9-12,17 and 19-44 are pending.

Continued Examination Under 37 CFR 1.114

2.   A request for continued examination under 37 CFR 1.114, including the fee set

forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this

application is eligible for continued examination under 37 CFR 1.114, and the fee set

forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action

has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on

10/11/07 has been entered.

Response to Amendment

The Examiner notes that the Applicant has copied claims 22-32 from the

Michelson et al US PAP 2006/0229916 (11/450,450) into the present application as

claims 34-44.

3.   The request for interference filed 10/11/07 is acknowledged. However,

examination of this application has not been completed as required by 37 CFR

41.102(a). Consideration of a potential interference is premature. See MPEP § 2303.

It should be noted that none of the claims in recited in and copied from the

Michelson et al published application have not been indicated as allowable or

patentable.   Likewise, none of the claims in the present application have been indicated

as allowable or patentable. Therefore, neither of the applications is in condition for

allowance and, the two applications are not subject to interference at this time.

Claim Rejections - 35 USC § 102

4.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5.   Claims 34-44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by

Michelson (US 2002/0002474 A1).

Claims 34-44 have been copied by applicant directly from (US 2002/0002474 A1) to

prematurely evoke an interference. Therefore, claims 34-44 are clearly anticipated by

claims 22-32 of the Michelson publication.

Claim Rejections - 35 USC § 103

6.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

7.   Claims 2-4, 9-12, and 17, 19-33 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Michelson et al (US 2002/0002474 A1) in view of Reddy et al (WO

01/93160 A1)

[claim 17] The limitations of amended claim 17 are addressed by the rejection of claims

19 and 23, and incorporated herein.

[claim 19] Michelson discloses a computer system for recruiting a patient into a clinical

trial, the system comprising components configured as at least:

 a server which: (par. 180)

-    requests patient-specific data from the patient, the patient-specific data

      requested including clinical trial eligibility data; (par. 80-82)

-    collects the patient-specific data from the patient; and (par. 82-83, 90)

-    send match result data to the patient; (par. 167-168)

a matcher responsive to the patient's clinical trial eligibility data and to trial-specific

criteria corresponding to the clinical trial to:

-    determine whether a match exists between the patient and the clinical trial; (par.

      83, and par. 166-167)

generate the match result data; and (167-168)

Michelson discusses the exchange of data in a secure environment among sponsors and investigators (par. 88). Michelson further discloses an Internet implemented system that uses a plurality of computers/databases, and but does not expressly disclose a system including a security layer.

Reddy discloses a clinical trials management system including a security layer (Figures 6-7) which:

- prevents direct communication between the server and the other workstations ; and receives the patient-specific data from the server;. (pg.16, line 7-13; pg. 17, lines 5-32)

The security layer disclosed by Reddy separates network server (e.g. the Internet server) and from the workstations. Furthermore patient data and secure transactions pass through the security layer (e.g. prevent direct communication b/n the server and the matcher). (pg.16, line 7-13; pg. 17, lines 5-32) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Michelson with the teaching of Reddy to include an added security layer. As suggested by Reddy, one would have been motivated to include this feature to prevent unauthorized user access (page 17, lines 5-8).

[claim 2] Michelson discloses system of claim 19, wherein the server communicates with the patient through a patient interface comprises an HTML-encoded web page. (par. 80, 89-91 –Internet implementation, webpage, Figures 6A-N)

[claim 3] Michelson discloses the system of claim 19, further comprising a patient

database in which patient-specific data is stored (par. 80-83; Figure 1B)

[claim 4] Michelson teaches the system of claim 19, further comprising a clinical trial

database, in which the set of trial specific criteria is stored (par. 88, par. 162-170, Figure

1A-1B)

[claim 9] Michelson discloses the system of claim 19, wherein the patient-specific data

comprises answers to a questionnaire. (par. 80-83 ; Figures 1A; 15A-E)

[claim 10] Michelson discloses a system configured to send at least a portion of the

patient-specific data to the clinical trial. (Figure 15E; par. 83)

[claim 11] Michelson teaches the system of claim 19, wherein the match result data

comprises clinical trial at least one of clinical contact and location information, and the

server is configured to send match data to the patient. (Figure 14; par. 167-169)

[claim 12] Michelson discloses a system wherein the patient-specific data comprises at

least one of disease of concern, demographic data, concomitant diseases, and

medications. (Figures 15A-E)

[Claim 20]   Michelson discloses the system of claim 19, wherein the system comprises

at least two computers. (pars. 80-82)

[claim 21] Michelson and Reddy the system of claim 20 as explained in the rejection of

claim 1, and 20.   Furthermore, Reddy discloses a system wherein the security layer

runs on one of the computers, and the matcher runs on another computer. (Figures 9-11; col. 14, lines 17-48) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Michelson with the teaching of Reddy for the reason provided in the rejection of claim 19.

[claims 22, 32]   Michelson discloses the system of claim 3 as explained in the rejection of claim 3. Michelson further discloses sending the patient-specific data to the patient database for storage only after the system determines whether a match exists between the patient and the clinical trial. (Figure 1B; par. 82-83, 168)

Michelson discusses the exchange of data in a secure environment among system users. (par. 88). Michelson further discloses an Internet implemented system that uses a plurality of computers/databases, and but does not expressly disclose a system including a security layer. Reddy discloses a system including a security layer (Figures 6-7) which prevents direct communication between the server and the other workstations and receives the patient-specific data from the server (pg.16, line 7-13; pg. 17, lines 5-32)The security layer disclosed by Reddy separates network server and from the workstations. Furthermore patient data and secure transactions pass through the security layer (e.g. prevent direct communication b/n the server and the matcher). (pg.16, line 7-13; pg. 17, lines 5-32)

At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Michelson with the teaching of Reddy to include an added security layer. As suggested by Reddy, one would have

been motivated to include this feature to prevent unauthorized user access (page 17,

lines, 29-32).

[claim 23] Michelson discloses a method of determining whether a patient is a

candidate for a clinical trial, comprising:

- serving a questionnaire from a server to a patient through a patient interface;
  (par. 80-83 ; Figures 1A; 15A-E)

- receiving at the server patient eligibility data submitted by the patient in response
  to the questionnaire; (par. 80,82-83, 89-91, Fig. 6A-N)

- sending the patient eligibility data from the server; (par. 80-83, 89-91, Fig. 1B)

- sending the patient eligibility data to a matcher; (par. 80-83, 89-91, Fig. 1B)

in the matcher:

- determining whether a match exists between the patient and the clinical trial by
  comparing the patient eligibility data to a set of trial criteria specific for the clinical
  trial; and (par. 166-167)

- returning match result information; (par. 167-168)

- sending to the server the match result information; and (par. 167-168)

- serving to the patient through the patient interface the match result information
  thus sent to the server. (par. 170)

  Michelson discusses the exchange of data in a secure environment among

system users. (par. 88). Michelson further discloses an Internet implemented system

that uses a plurality of computers/databases, and but does not expressly disclose a

system including a security layer. Reddy discloses a system including a security layer

(Figures 6-7) which prevents direct communication between the server and the other

workstations and receives the patient-specific data from the server (pg.16, line 7-13; pg.

17, lines 5-32)The security layer disclosed by Reddy separates network server and

from the workstations. Furthermore patient data and secure transactions pass through

the security layer (e.g. prevent direct communication b/n the server and the matcher).

(pg.16, line 7-13; pg. 17, lines 5-32)

      At the time of the applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the system/method of Michelson with the teaching of

Reddy to include an added security layer. As suggested by Reddy, one would have

been motivated to include this feature to prevent unauthorized user access (page 17,

lines, 29-32).

[claim 24] Michelson discloses a method, further comprising serving at least one of

clinical trial contact and location information to the patient through the patient interface.

(par. 169)

[claim 25]   Michelson discloses a method further comprising serving a registration

questionnaire to the patient through the patient interface after a match has been

determined to exist between the patient and the clinical trial. (par. 168)

[claim 26] Michelson discloses a method further comprising receiving a set of

registration information from the patient. (par. 168)

[claim 27]   Michelson discloses a method further comprising adding the registration

information to a patient database. (par. 168; Figure 24—subject database)

[claim 28] Michelson discloses a method further comprising sending at least part of the

set of registration information to the clinical trial. (par. 169-170)

[claim 29] Michelson disclose a method further comprising comparing, in the matcher,

the patient eligibility data to a second set of trial criteria and determining whether a

match continues to exist between the patient and the clinical trial. (par. 169, 172)

 [claim 30]   Michelson and Reddy the system of claim 23 as explained in the rejection

of claim 23.   Michelson discloses a system comprising at least two computers, (pars.

80-82), but does not specifically disclose a security layer.   Reddy discloses a system

wherein the security layer runs on one of the computers, and the matcher runs on

another computer. (Figures 6-7; pg.16, line 7-13; pg. 17, lines 5-32) At the time of the

applicant's invention, it would have been obvious to one of ordinary skill in the art to

modify the system of Michelson with the teaching of Reddy for the reason provided in

the rejection of claim 19.

[claim 31]   Michelson discloses a method of determining whether a patient is a
candidate for a clinical trial, comprising:

- serving a first questionnaire from a server to a patient through a patient
  interface; (par. 80-83 ; Figures 1A; 15A-E)

- receiving at the server a first set of patient eligibility data submitted by the
  patient in response to the first questionnaire; (par. 80,82-83, 89-91, Fig. 6A-N)

- sending the first set of patient eligibility data from the server; (par. 80-83, 89-91,
  Fig. 1B)

- sending the first set of patient eligibility data from the security layer to a matcher;
  (par. 80-83, 89-91, Fig. 1B)

in the matcher:

- determining whether a match exists between the patient and the plurality of
  clinical trials by comparing the first set of patient eligibility data to a set of generic
  trial criteria generic to a plurality of clinical trials; and (par. 166-167)

- returning generic match result information; (par.166-167))

- if a match exists between the patient and the plurality of clinical trials:

    o serving a second questionnaire from the server to the patient through the
      patient interface; (par. 168)

    o receiving at the server a second set of patient eligibility data submitted by
      the patient in response to the second questionnaire; (par. 168-169)

    o sending the second set of patient eligibility data from the server (par. 168-
      169)

- o sending the second set of patient eligibility data ; (par. 168-169)

in the matcher:

- determining whether a match exists between the patient and the one clinical trial
  by comparing the second set of patient eligibility data to a set of specific trial
  criteria specific to one of the plurality of clinical trials; and (par. 169, 172)

- returning specific match result information; (par. 169-170)

- if a match exists between the patient and the one clinical trial:

  - o sending information about the one clinical trial ; and (par. 169-170)

  - o serving the clinical trial information to the patient through the patient
    interface. (par. 169-170)

Michelson discusses the exchange of data in a secure environment among
system users. (par. 88). Michelson further discloses an Internet implemented system
that uses a plurality of computers/databases, and but does not expressly disclose a
system including a security layer.

Reddy discloses a system including a security layer (Figures 6-7) which prevents
direct communication between the server and the other workstations and receives the
patient-specific data from the server (pg.16, line 7-13; pg. 17, lines 5-32).
The security layer disclosed by Reddy separates network server (e.g. the Internet
server) and from the workstations. Furthermore patient data and secure transactions
pass through the security layer (e.g. prevent direct communication b/n the server and
the matcher). (Figures 6-7; pg.16, line 7-13; pg. 17, lines 5-32) At the time of the
applicant's invention, it would have been obvious to one of ordinary skill in the art to

modify the system/method of Michelson with the teaching of Reddy to include an added

security layer. As suggested by Reddy, one would have been motivated to include this

feature to prevent unauthorized user access (pg.16, line 7-13; pg. 17, lines 5-32).

[claims 33]   Michelson discloses the system of claim 19 as explained in the rejection of

claim 3. Michelson further discloses sending the patients clinical trial eligiblitiy data, but

not other data to matcher. (Figure 1B; par. 82-83, 168)

        Michelson discusses the exchange of data in a secure environment among

system users. (par. 88). Michelson further discloses an Internet implemented system

that uses a plurality of computers/databases, and but does not expressly disclose a

system including a security layer. Reddy discloses a system including a security layer

(Figures 6-7) which prevents direct communication between the server and the other

workstations and receives the patient-specific data from the server (pg.16, line 7-13; pg.

17, lines 5-32)The security layer disclosed by Reddy separates network server and

from the workstations. Furthermore patient data and secure transactions pass through

the security layer (e.g. prevent direct communication b/n the server and the matcher).

(pg.16, line 7-13; pg. 17, lines 5-32)

         At the time of the applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the system/method of Michelson with the teaching of

Reddy to include an added security layer. As suggested by Reddy, one would have

been motivated to include this feature to prevent unauthorized user access (page 17,

lines, 29-32).

Response to Arguments

8.   Applicant's arguments have been considered but are moot in view of the new

ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to RACHEL L. PORTER whose telephone number is

(571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

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For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./
Examiner, Art Unit 3626

/C. Luke Gilligan/
Primary Examiner, Art Unit 3626